PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Mark J. RATAIN et al.

Serial No.: 10/591,484

Filed: September 1, 2006

For: METHODS AND COMPOSITIONS RELATING TO THE PHARMACOGENETICS OF DIFFERENT GENE VARIANTS

Group Art Unit: 3662

Examiner: Unknown

Atty. Dkt. No.: ARCD:405US

Confirmation No.: 9362

CERTIFICATE OF ELECTRONIC TRANSMISSION

I hereby certify that this correspondence is being electronically filed with the United States Patent and Trademark Office via EFS-Web on the date below:

June 14, 2007
Date

Gina N. Shishima

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/ARCD:405US.

This application may be related by inventorship and subject matter to U.S. application numbers:

08/423,641, filed April 17, 1995, issued as U.S. Patent No. 5,786,344;

09/251,274, filed February 16, 1999, under reexam as U.S. application no. 90/007,601;

09/553,829, filed April 21, 2000, now abandoned;

09/835,082, filed April 12, 2001, now abandoned;

10/057,834, filed January 25, 2002, now abandoned;

10/061,693, filed February 1, 2002, issued as U.S. Patent No. 6,472,157;

10/277,160, filed October 21, 2002, now abandoned;

10/591,228, filed August 31, 2006;

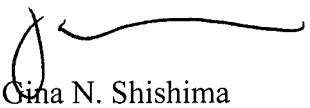
10/558,510, filed October 23, 2006;

10/751,606, filed January 5, 2004;

11/561,341, filed November 17, 2006.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



Gina N. Shishima
Reg. No. 45,104
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 474-5201

Date: June 14, 2007

Form PTO-1449 (modified)	Atty. Docket No. ARCD:405US	Serial No. 10/591,484
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant Mark J. RATAIN *et al.*	
	Filing Date: September 1, 2006	Group: 3662

U.S. Patent Documents	Foreign Patent Documents	Other Art
See Page 1	*See Page 1*	*See Pages 1-5*

U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	09/553,829	4/21/00	Ratain *et al.*	514	9	4/21/00
	A2	2002-0016293	2/7/02	Ratain *et al.*	514	9	4/12/01
	A3	2003-0099960	5/29/03	Ratain *et al.*	435	6	1/25/02
	A4	2003-0152968	8/14/03	Di Rienzo *et al.*	435	6	10/21/02
	A5	2004/0203034	10/14/04	Ratain *et al.*	435	6	1/5/04
	A6	2007-0092902	4/26/07	Di Rienzo *et al.*	435	6	11/17/06
	A7	5,786,344	7/28/98	Ratain and Gupta	514	100	4/17/95
	A8	6,395,481	5/28/02	Di Rienzo *et al.*	435	6	2/16/99
	A9	6,395,481	5/28/02	Di Rienzo *et al.*	435	6	2/16/99
	A10	6,472,157	10/29/02	Di Rienzo *et al.*	435	6	2/1/02

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Language
		WO 2005/085473	9/15/05	WIPO	English
		WO 2004/108954	12/16/04	WIPO	English

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Ando *et al.*, "Polymorphisms of UDP-glucuronosyltransferase gene and irinotecan toxicity: a pharmacogenetic analysis," Cancer Res., 60(24):6921-6926, 2000.
	C2	Araki *et al.*, "Relationship between development of diarrhea and the concentration of SN-38, an active metabolite of CPT-11, in the intestine and the blood plasma of athymic mice following intraperitoneal administration of CPT-11," *Jpn. J. Cancer Res.*, 84:697-702, 1993.

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EXAMINER:	DATE CONSIDERED:

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	C3	Beutler *et al.*, "Racial variability in the UDP-glucuronosyltransferase 1 (UGT1A1) promoter: a balanced polymorphism for regulation of bilirubin metabolism?" *Proc. Natl. Acad. Sci. USA*, 95(14):8170-8174, 1998.
	C4	Borst *et al.*, "A family of drug transporters: the multidrug resistance-associated proteins," *J. Natl. Cancer Inst.*, 92:1295-1302, 2000.
	C5	Borst *et al.*, "The multidrug resistance protein family," *Biochim. Biophys. Acta,* 1461(2):347-357, 1999.
	C6	Bosma *et al.*, "Sequence of exons and the flanking regions of human bilirubin-UDP-glucuronosyltransferase gene complex and identification of a genetic mutation in a patient with Crigler-Najjar syndrome, type I," *Hepatology*, 15(5):941-947, 1992.
	C7	Bosma *et al.*, "The genetic basis of the reduced expression of bilirubin UDP-glucuronosyltransferase 1 in Gilbert's syndrome," *N. Eng. J. Med.*, 333:1171-1175, 1995.
	C8	Fang *et al.*, "Correlation between the UDP-glucuronosyltransferase (UGT1A1) TATAA box polymorphism and carcinogen detoxification phenotype: significantly decreased glucuronidating activity against benzo(a)pyrene-7,8-dihydrodiol(-) in liver microsomes from subjects with the UGT1A1*28 variant," *Cancer Epidemiology, Biomarkers & Prevention*, 13:102-109, 2004.
	C9	Fuchs *et al.*, "Phase III comparison of two irinotecan dosing regimens in second-line therapy of metastatic colorectal cancer," *J. Clin. Oncol.*, 21:807-814, 2003.
	C10	Gerk & Vore, "Regulation of expression of the multidrug resistance-associated protein 2 (MRP2) and its role in drug disposition," *J. Pharmacology And Experimental Therapeutics*, 302(2):407-415, 2002.
	C11	Guillemette *et al.*, "Genetic polymorphisms in uridine diphospho-glucuronosyltransferase 1A1 and association with breast cancer among African Americans," *Cancer Res.*, 60:950-956, 2000.
	C12	Gupta *et al.*, "Metabolic fate of irinotecan in humans: correlation of glucuronidation with diarrhea," *Cancer Res.*, 54:3723-3725, 1994.
	C13	Gupta *et al.*, "Pharmacokinetic and pharmacodynamic evaluation of the topoisomerase inhibitor irinotecan in cancer patients," *J. Clin. Oncol.*, 15:1502-1510, 1997.

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	C14	Innocenti *et al.*, "Pharmacogenetic analysis of interindividual irinotecan (CPT-11) pharmacokinetic (PK) variability: Evidence for a functional variant of *ABCC2*," *J. Clinical Oncology, Supplement*, 22(14s):2010, July 2004.
	C15	Ito *et al.*, "Polymorphism of the ABC transporter genes, MDR1, MRP1 and MRP2/cMOAT, in healthy Japanese subjects," *Pharmacogentics*, 11(2):175-184, 2001.
	C16	Itoda *et al.*, "Polymorphisms in the ABCC2 (cMOAT/MRP2) gene found in 72 established cell lines derived from Japanese individuals: an association between single nucleotide polymorphisms in the 5'-untranslated region and exon 28," *Drug Metaboloism And Disposition*, 30(4):363-364, 2002.
	C17	Iyer *et al.*, "Genetic predisposition to the metabolism of irinotecan (CPT-11). Role of uridine diphosphate glucuronosyltransferase isoform 1A1 in the glucuronidation of its active metabolite (SN-38) in human liver microsomes," *J. Clin. Invest.*, 101:847-854, 1998.
	C18	Iyer *et al.*, "Phenotype-genotype correlation of in vitro SN-38 (active metabolite of irinotecan) and bilirubin glucuronidation in human liver tissue with UGT1A1 promoter polymorphism," *Clinical Pharmacology & Therapeutics,* 65(5):576-582, 1999.
	C19	Iyer *et al.*, "UGT1A1*28 polymorphism as a determinant of irinotecan disposition and toxicity," *J. Phamacogenomics*, 2:43-47, 2002.
	C20	Johnson *et al.*, "Haplotype tagging for the identification of common disease genes," *Nat. Genet.*, 29(2):233-237, 2001.
	C21	Kaneda *et al.*, "Metabolism and pharmacokinetics of the camptothecin analogue CPT-11 in the mouse," *Cancer Res.*, 50:1715-1720, 1990.
	C22	Ke and Cardon, "Efficient selective screening of haplotype tag SNPs," *Bioinformatics*, 19(2):287-288, 2003.
	C23	Kwok and Chen, "Detection of single nucleotide polymorphisms," *Curr Issues Mol. Biol.*, 5(2):43-60, 2003.
	C24	Kwok, "Methods for genotyping single nucleotide polymorphisms," *Annu Rev Genomics Hum Genet.*, 2:235-258, 2001.
	C25	Mathijsen *et al.*, "Irinotecan pathway genotype analysis to predict pharmacokinetics," *Clinical Cancer Research*, 9:3246-3253, 2003.

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	C26	Monaghan *et al.*, "Genetic variation in bilirubin UPD-glucuronosyltransferase gene promoter and Gilbert's syndrome," *Lancet,* 347:578-581, 1996.
	C27	Negoro *et al.*, "Phase I study of weekly intravenous infusions of CPT-11, a new derivative of camptothecin, in the treatment of advanced non-small-cell lung cancer," *J. Natl. Cancer Inst.*, 83(16):1164-1168, 1991.
	C28	Niemi *et al.*, "High plasma pravastatin concentrations are associated with single nucleotide polymorphisms and haplotypes of organic anion transporting polypeptide-C (OATP-C, SLCO1B1)," *Pharmacogenetics*, 7:429-440, 2004.
	C29	Nozawa *et al.*, "Role of organic anion transporter OATP1B1 (OATP-C) in hepatic uptake of irinotecan and its active metabolite, 7-ethyl-10-hydroxycamptothecin: in vitro evidence and effect of single nucleotide polymorphisms," *Drug Metab Dispos.*, 33(3):434-439, 2005.
	C30	Owens & Ritter, "Gene structure at the human UGT1 locus creates diversity in isozyme structure, substrate specificity, and regulation," *Prog. Nucleic Acid Res. Mol. Biol.*, 51:305-338, 1995.
	C31	Ritter *et al.*, "A novel complex locus UGT1 encodes human bilirubin, phenol, and other UDP-glucuronosyltransferase isozymes with identical carboxyl termini," *J. Biol. Chem.*, 267(5):3257-3261, 1992.
	C32	Rothenberg *et al.*, "Phase I and pharmacokinetic trial of weekly CPT-11," *J. Clin. Oncol.*, 11(11):2194-2204, 1993.
	C33	Sparreboom and Nooter, "Does P-glycoprotein play a role in anticancer drug pharmacokinetics?" *Drug Resist. Update.*, 3:357-363, 2000.
	C34	Sugatani *et al.*, "Identification of a defect in the UGT1A1 gene promoter and its association with hyperbilirubinemia," *Biochem. Biophys. Res. Commun.*, 292:492-497, 2002.
	C35	Suzuki and Sugiyama, "Excretion of GSSG and glutathione conjugates mediated by MRP1 and cMOAT/MRP2," *Semin. Liver. Dis.* 18:359-376, 1998.
	C36	Suzuki and Sugiyama, "Single nucleotide polymorphisms in multidrug resistance associated protein 2 (MRP2/ABCC2): its impact on drug disposition," *Advance Drug Delivery Reviews*, 54(18):1311-1331, 2002.

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	C37	Suzuki *et al.*, "Transporters for bile acids and organic anions," in: G.L. Amidon, W. Sadec (eds.), Membrane Transporters as Drug Targets, Kluwer Academie/Plenum Publishers, New York, 1999.
	C38	Takasuna *et al.*, "Study on the mechanisms of diarrhea induced by a new anticancer camptothecin derivative, irinotecan hydrochloride (CPT-11), in rats," *Nippon Yakurigaku Zasshi*, 105(6):447-460, 1995.
	C39	Tukey and Strassburg, "Human UDP-glucuronosyltransferases: metabolism, expression, and disease," *Annu. Rev. Pharmacol. Toxicol.*, 40:581-616, 2000.
	C40	Vanhoefer *et al.*, "Irinotecan in the treatment of colorectal cancer: clinical overview," *J. Clin. Oncol.*, 19(5):1501-18, 2001.

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